

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO ALL CASES	HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)

**CERTIFICATION OF C. BRETT VAUGHN IN SUPPORT OF
PLAINTIFFS' DAUBERT MOTION TO EXCLUDE TESTIMONY OF
MICHAEL B. BOTTORFF, PHARM. D.**

C. BRETT VAUGHN, hereby certifies as follows:

1. I am an attorney at law within the State of Kansas with the Hollis Law Firm, and serve on the Plaintiff's Executive Committee. I am fully familiar with the facts and circumstances of these actions. I make this Certification in support of Plaintiffs' motion to exclude the testimony of Michael B. Bottorff, Pharm. D.
2. Attached hereto as **Exhibit A** is a true and accurate copy of the September 16, 2021 Deposition Transcript of Michael Bottorff.
3. Attached hereto as **Exhibit B** is a true and accurate copy of World Health Org. [WHO], *N-Nitrosodimethylamine*, Concise International Chemical Assessment Document 38 (2002).
4. Attached hereto as **Exhibit C** is a true and accurate copy of Michael Bottorff's Report.

5. Attached hereto as **Exhibit D** is a true and accurate copy of U.S. Dep't Health & Human Services, FDA, & CDRH, *Control of Nitrosamine Impurities in Human Drugs: Guidance for Industry*, Current Good Manufacturing Processes, Rev. 1 (Feb 2021).

6. Attached hereto as **Exhibit E** is a true and accurate copy of Richard Peto, et al., *Effects on 4080 Rats of Chronic Ingestion of N-Nitrosodiethylamine or N-Nitrosodimethylamine: A Detailed Dose-Response Study*, CANCER RES. 51:6415-6451 (Dec. 1991).

7. Attached hereto as **Exhibit F** is a true and accurate copy of N. Ito, et al., *Induction of Preneoplastic and Neoplastic Lesions in Rats Treated N-Nitroso Compounds*, IARC Scientific Pub No. 41, 597-601 (WHO 1982).

8. Attached hereto as **Exhibit G** is a true and accurate copy of *Player v. Motiva Enterprises LLC*, No. Civ. 02–3216(RBK), 2006 WL 166452 (D.N.J. January 20, 2006).

HOLLIS LAW FIRM
Attorneys for Plaintiffs

Dated: November 1, 2021

By: /s/ C. Brett Vaughn
C. Brett Vaughn RN, BSN, JD
Hollis Law Firm
8101 College Blvd, Suite 260
Overland Park, KS 66210
Ph: 913-385-5400
Fax: 913-385-5402
Brett@HollisLawFirm.com